Association of Food and Drug Officials

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Department of Health and Human Services
Food and Drug Administration

RE: Comments from the Association of Food and Drug Officials
Docket No. FDA-2011-N-0920, "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food Proposed Rule"

The Association of Food & Drug Officials (AFDO) is a national organization that represents state, local, and federal food, drug, and medical device safety regulatory officials. AFDO is well known for promoting uniformity and cooperation among the regulatory community and has helped to foster numerous collaborative projects to advance these objectives. Among the national projects AFDO was active in developing and promoting are the Seafood HACCP Alliance, National Food Safety System (NFSS) project, States Helping States project, the International Food Protection Training Institute (IFPTI), and FoodSHIELD. Additionally, AFDO has developed a host of model codes that states utilize in promulgating their own specific regulations. AFDO model codes such as our "Cured Salted and Smoked Fish GMP's", "Guidelines for Juice Manufacturers", "Produce Safety Model Code", "Retail Meat & Poultry Processing at Retail Guidelines" and "Reduced Oxygen Packaging at Retail" were authored following outbreaks and specific food safety issues associated with these types of food products and their processing methods. A number of federal and state standards and regulations were developed in part from the information contained within these model codes. Because of AFDO's strong association with state food safety programs, the organization is in a unique position to promote food safety projects that will help to advance a national integrated food safety system which AFDO has advocated for over 15 years.

Most states have adopted 21 CFR Part 110; Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, in whole or in part, and it is generally recognized that this regulation serves as the foundation for all others which have been promulgated for food manufacturing at the state level. State regulations specific to smoked fish, low acid canned foods, acidified foods, food salvage dealers and other food processing and food storage establishment types are built from the regulatory standards provided in 21 CFR Part 110. For this reason, AFDO believes the proposed regulation relating to preventive controls must be complete and comprehensive. AFDO has always believed that controlling food safety in commercial food establishments through a preventative approach using hazard analysis, identification of prevention controls, monitoring, and verification is a systematic remedy to food safety and should be employed universally to all food industry sectors.

It is clear that uniformity among all regulatory agencies is critical to FDA, the States, industry and consumers. As states perform more than 80 percent of all food safety inspections of food processors and distributors and approximately 8,000 contract inspections annually under contract for FDA, AFDO believes FDA must work very closely with the states on implementing the newly proposed regulation. Implementation will take

time and AFDO recommends that FDA and the states remain engaged in this process through established Alliances including the Manufactured Food Regulatory Program Alliance (MFRPA) administered by AFDO, and the Food Safety Preventive Control Alliance (FSPCA) administered by the Institute for Food Safety & Health (IFSH).

While AFDO strongly supports the enactment of the proposed rule, we also recognize that it will take an active partnership and an integrated government effort to meet the demands of the proposed rule in terms of inspection and enforcement. **The proposed rule will only be effective if government agencies enforce it.**

Many of the recent foodborne illness outbreaks that have occurred in this country were investigated by a number of our members and following each of these outbreaks, questions were raised as to the current effectiveness of government food safety activities. Our comments to FDA are provided with the understanding that government must address food safety concerns in an integrated manner that can begin in a similar progressive fashion as conducted for fishery products, meat & poultry, shell eggs, and vegetable juices.

AFDO has members active in the Food Safety Preventive Controls Alliance (FSPCA) Steering Committee and the various Working Groups that were established within this Alliance. At this time AFDO will provide comments that relate to the proposed rule in general and may provide more specific comments at a later date.

In addition, AFDO is providing comment and working with the National Association of State Departments of Agriculture (NASDA) on more specific comments relating to the various Subparts of the proposed rule. AFDO may, also, provide additional specific comments at a later date.

Our general comments are as follow:

1) Communication with State Agencies and State Partners

FDA must foster regular communication and information exchange with state partners and other state and federal agencies. Further development and implementation of the Preventive Control Rule will require a coordinated effort from FDA and its state partners. Because state agriculture agencies work closely with farmers and the farm mixed-type facilities which are addressed in this rule, they are acutely aware of the challenges producers will face. Moreover, State Agriculture agencies each have varying levels of authority and food safety responsibilities. The differences and nuances in state structure and authority will make implementation at each state a unique challenge. In our view, it is *essential* that FDA establish regular and open communication with state organizations (such as NASDA and AFDO) in addition to communicating directly with states. FDA must comprehensively and consistently answer questions, address individual concerns, and listen to input from its partners. While AFDO appreciates FDA's intent to provide a better food safety framework, if State and Federal agencies fail to effectively implement FSMA or mixed-facility operators are unable to comply, the rules will fail.

Open communication is essential to FSMA's success, and AFDO hopes FDA will facilitate more dialogue with stakeholders and state governments prior to issuing the final Preventive Controls Rule. We believe that standardized mechanisms of communication between FDA and state governments be established before, during and after final rulemaking to ensure well-coordinated implementation. FDA should continue to participate in forums or question and answer panels at AFDO and AFDO affiliate meetings that are attended by state program managers. Additionally, after the comment period ends, AFDO urges the FDA to continue to engage stakeholders.

2) Exemptions

In relation to the provisions relating to exemptions and modified preventive control requirements, AFDO opposes these on the grounds they are unenforceable. How will determinations be made to assure a facility has food sales averaging less than $500,000 per year during the last three years? Will there be a process for establishing and removing exemptions? Who will verify that sales are located in the same state and are not more than 275 miles away? The limited inspection resources that currently exist should not be devoted to determining the annual sales of an establishment or the miles they distribute from their location.

We have learned from the past that an entire industry can be negatively impacted by the smallest of operations. Exempting small business or modifying preventive control requirements is unwise, in our view.

We do not believe it is at all unreasonable to expect commercial manufacturers of food that will be consumed by humans to be required to conduct a hazard analysis of their operation and include risk based preventive control requirements where necessary to assure the food manufactured is safe. The idea that one establishment is exempted from this rule until such time that their products have been found contaminated does not make sense from a public health perspective. Exemptions create an uneven playing field and put more of a burden on retailers who receive products from exempted firms.

On the FDA Fact Sheet for this proposed rule there is an Exemption Table which indicates that grain elevators and warehouses that store only raw agricultural commodities would be exempt from the Current Good Manufacturing Practices (CGMP's). AFDO does not support exempting grain elevators storing commodities and food warehouses which store unrefrigerated package foods from the requirements of the CGMP rule. While we would agree these food establishments would not be a high risk type that would require frequent inspections, we cannot support exempting any commercial food manufacturing, storage, or commodity storage facility from CGMP requirements. How, for instance, would pest control be regulated here?

AFDO requests clarification on frozen foods and whether FDA considers frozen food to be a subset of refrigerated food which would, therefore, not be exempted from CGMP requirements. Restaurants are exempt from the proposed preventive controls rules, as they are not required to register with the FDA. The term "Restaurant", however, does not include central kitchens that may distribute prepared food to other schools in their district. Since this does not fit into the definition of a "Restaurant", would the preventive controls rule apply to these operations? Are commissary kitchens exempt from preventive controls?

3) Definitions

The definition of small business is based on number of employees but options for the definition of very small businesses are based on income. These definitions should be consistent.

4) Frequency of Inspection

FSMA legislation requires inspections to be based on risk, and the frequency of inspections to increase as the risk increases. It calls for all high risk domestic food facilities to be inspected within five years of the bill's signing and then at least once every three years after that. Further, all other domestic food facilities are to be inspected within seven years of the bill's signing and then at least once every five years thereafter.

The frequency of inspection for domestic facilities is very weak, in our view, and does not provide adequate coverage of these facilities. Furthermore, it demeans the intent of the proposed rule which is to prevent foodborne illness. If food safety inspection is truly important, high risk food facilities must be inspected more

than once every three years. FDA must work closely with its state partners who currently inspect these facilities at least annually and in some cases multiple times during the year. In our opinion, this would be a prime area where integration of food safety systems can have a huge impact. FDA should expand its working efforts with states in the Manufactured Food Regulatory Program Alliance (MFRPA) and assist in the expansion of the Manufactured Food Regulatory Program Standards (MFRPS) into all state agencies who perform manufactured food inspections. By establishing inspection equivalence among all state agencies and FDA, the frequency of inspection can be set at a more reasonable rate, but at least annually.

Also noted in the proposed rule is that certain commodities are considered low risk, until the producers makes over a certain amount of money. What was the intention behind this and what public health principles were considered when making this determination?

5) Role of the States

It is clear that FDA will need to collaborate with state food safety agencies in order to meet the mandates of this proposed rule yet the oversight and responsibilities of these agencies is not well defined. Depending on the number and types of facilities that will fall under this proposed rule, and depending on what FDA delegates to states, it is possible that states may not have the resources to carry out the inspections and possible environmental microbial testing required by this rule. AFDO recently conducted for FDA a survey of state and local food safety agencies that will help to identify capacity needs for these agencies. This survey should assist FDA in determining which agencies can better help them meet the demands of the proposed rule.

Until this point, only conceptual discussions between current state and federal food safety personnel have occurred regarding the potential institutional relationships that may be needed to implement FSMA. State-level agencies need to have discussions with FDA about the state-federal relationship in terms of delegation of authority and who will be responsible for enforcement once the rules are in force. AFDO understands that dialogue between state and federal officials will occur independently of the drafting of rules to implement FSMA; however, the structure of these new institutional relationships should be established as soon as possible.

Throughout the proposed Rules, FDA clearly intends to have states agencies involved in implementation of the final Preventive Controls. While food safety authority often rests in the state departments of agriculture, in some states the existing primary authority rests in another state agency (public health, consumer services, etc.). The involvement of these state-level departments currently responsible for food safety, in coordination with their agriculture departments, is essential to the success of the Preventive Controls Rule because the agriculture departments will be instrumental in bringing the farm mixed-type facilities into the realm of preventive regulations and inspections for the first time. Alternatively, states may be able to contract with FDA to conduct FDA inspections using federal credentials.

Some states currently lack jurisdictional authority to conduct a State Food Safety Program in compliance with the expanded scope of FSMA. Concurrent with the development of the federal rules, states need to be assessing the current division of roles and institutional relationships between agriculture and health for current food safety or food processing regulatory authority and any lack of authority to conduct a new food safety program in compliance with FMSA requirements. This requires involvement of FDA as some level of consistency needs to be assured among the states. FDA's timeline for FSMA implementation does not provide adequate time for states to seek and implement new regulatory authority. FDA should share their thoughts on this potential timeline and how it affects rule implementation?

State departments of agriculture should participate in the implementation of FSMA and integration of state and federal food safety systems; however, many state officials are concerned about the lack of information FDA has

provided on the nature of our cooperation. What mechanisms will FDA use to delegate authority to the states? Will FDA create commissions or credentialing of state personnel to conduct the inspections? If a state chooses not to participate in FSMA, will FDA choose to implement the rules with its own inspectors? Exactly how inspections will be carried out and the structure of state-federal relationships must be established in order to ensure uniform enforcement among states. AFDO recommends FDA clarify its position on compliance efforts that will result from the proposed rule. FDA should be mindful that states traditionally include educational assistance in current compliance efforts for food manufacturing and retail establishments. What is FDA's position on state application of educational methods of compliance for produce growers and packers impacted by this proposed rule? It is unclear whether FDA or the states will conduct compliance efforts and whether there will be graduated sanctions applied when necessary.

6) Pasteurized Milk Ordinance

There is some confusion as to whether these proposed regulations would apply to dairy firms which follow the Pasteurized Milk Ordinance (PMO) and AFDO requests clarification on this matter.

Will FDA recognize the current national system of regulating Grade "A" milk and milk products under the PMO and the National Conference on Interstate Milk Shipments (NCIMS) as being equivalent to the requirements of the proposed Preventive Controls Rule thus exempting those milk processing plants regulated under the PMO from the requirements of the proposed Preventive Controls Rule?

AFDO does not believe an additional burden should be placed upon firms that must comply with the PMO. We also recognize, however, that a dairy plant producing products in conformance with the PMO may produce other products that are not covered by the ordinance. We would not support exempting these products from the requirements of this proposed rule.

7) System to Arbitrate Disputes

FDA must consider developing a review system to arbitrate disputes between industry and government over the identification of risk based preventive control requirements. The system should be real-time so these matters can be resolved in a timely fashion. What may be challenging to food processors is the regulatory environment under which the rule will be implemented and managed. While the prevention concept is flexible, FDA and state regulators have their own set of biases about what constitutes a hazard in a specific manufacturing process and what type of documentation is appropriate to ensure compliance. There will be disputes and FDA should establish a system for responding to these.

8] Qualified Individual

In addition to conducting a hazard analysis of their operation and creating risk based preventive plans that will pass the scrutiny of FDA and state regulators, food companies will also need to demonstrate that their preventive plans were designed by a "qualified individual." This is a very subjective term and more clarity needs to be established for this term. At a very minimum, the completion of a FDA recognized program, as is being developed through the Food Safety Preventive Controls Alliance (FSPCA), should be required. FDA should work with FSPCA, IFPTI, and AFDO in establishing an appropriate recordkeeping and verification system for individuals who have successfully completed this course. In our view, this system should be similar to the current system in place for the Seafood HACCP Alliance (SHA).

9) Plan Preapproval

FDA did not require the submission of plans for preapproval in the proposed human rule. AFDO recommends that at a minimum a subset of information that would be in a food safety plan should be provided. This information should include: contact information; facility type; products manufactured; hazards identified; preventive controls; third-party audit information; training information; facility size (square footage); and operations schedule. AFDO believes it is important that preapproval of this basic information be conducted prior to an inspection. Field inspectors should not have the added burden of validating food safety plans during inspections when verification of these plans is occurring.

10) Testing

FDA did not include requirements to test raw materials, ingredients and finished products. However, FDA states that it believes testing "plays a very important role in ensuring the safety of food". AFDO agrees and recommends that FDA determine areas, product types, and facility types where testing should be required.

11) Environmental Testing

The proposed rule would require that the hazard analysis include an evaluation of whether environmental pathogens are reasonably likely to occur whenever a ready to eat (RTE) food is exposed to the environment prior to packaging. Environmental pathogens can be a source of contamination of food. Examples of environmental pathogens that have contaminated RTE foods include *Salmonella* spp. and *L. monocytogenes*. A facility that produces an RTE food that is exposed to the environment would be required to identify environmental pathogens as a known or reasonably foreseeable hazard and evaluate whether contamination of RTE food with the environmental pathogen is reasonably likely to occur in the facility. AFDO is unclear how this can be properly evaluated without requiring environmental testing. Our feeling is that environmental testing should be required in food manufacturing establishments where RTE food products are produced.

12) Verification

FDA did not include supplier verification and approval program requirements in the proposed rule, but states data indicate that almost 40 percent of Class I and Class II recalls that occurred during 2008-09 were directly linked to the lack of supplier controls. AFDO believes these verification requirements should be included in the rule. These can include on-site audits, testing, and a review of supplier food safety plans and records.

13) Imports

These proposed rules must be part of an overall system that will include the remaining and yet to be released import regulations. AFDO hopes that these rules can be published very soon so their enactment dates will coincide with the recently released rules and to ensure an appropriate level of consistency for food manufacture.

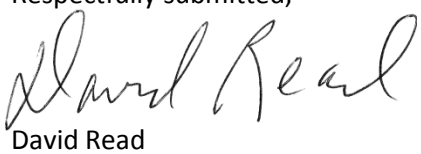
14) Good Manufacturing Practices [GMP's]

Most states have adopted 21CFR Part 110, Current GMP's in Manufacturing, Packing, or Holding Human Food and have actually cited the section numbers on their inspection reports and checklists**.** As a result many state programs would have preferred that Part 110 was amended rather than repealed for the new part 117.

AFDO recognizes the importance of and supports the requirement for food plants to have a written recall plan to follow in the case where a manufactured product must be removed from the marketplace. We do not believe this will place an excessive burden on industry as many model plans are available including one AFDO developed with the University of Florida under a grant with the Department of Defense. In our view, access to a written recall plan is critical in the event of a system breakdown where adulterated foods have been distributed and must be recalled. FDA has requested comment as to whether any recall plan should include a completed mock recall that has verified the effectiveness of the recall plan. AFDO believes that while a mock recall is an important element of a recall plan, it should not be mandated in the final rule.

The FDA Food Safety Modernization Act (FSMA) is the most sweeping reform of our food safety laws in more than 70 years. This proposed rule under FSMA should be as sweeping as the statute that has allowed it. AFDO is fully supportive of the proposed rule and energized to assist in any way we can to implement it fully. Creating exemptions and limiting the scope of the regulations will only create gaps and weaken the food safety system we are trying so hard to create. This is a historic opportunity for food protection and FDA must take full advantage, in our view.

Respectfully submitted,



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